OPERATOR'S GUIDE

Infusion Workstation

orchestra®

Base Intensive

CE 0459

Introduction

Base Intensive Orchestra® offers a unique solution in CCU, ICU and anaesthesia.

The **Base Intensive Orchestra®**:

- Brings additional performances.
- Facilitates and secures drug programming.
- Uses a multi-channel infusion pump potentialities.
- Summarises the infusion data at patient bed.
- Communicates, via a unique serial cable, parameters to a centralised system of PDMS (Patient Data Management System).

User interface is underlined by the color screen and an ergonomic command for more safeties and user friendliness.

According to the number of intravenous infusions needed, at any combination, from 1 to 8 **Module MVP** or **Module MVP+** or **Module DPS** or **Module DPS Visio** or **Module DPS+** (up to 14 or 16 Modules if **Base Intensive** is connected to **Base A**) can be fitted onto the **Base Intensive Orchestra®**.

The use of this material requires great care. The user must be able to handle the instrument properly and must know how to fully operate.

Please read the operator's guide carefully before putting the device into use.

Prior to any use of Modules with the **Base Intensive Orchestra®**, please refer to the **Module DPS, Module DPS Visio, Module DPS+, Module MVP and Module MVP+ Orchestra®** Operator's Guides.

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Fresenius Vial Infusion Technology

Installation of Modules (Module DPS, Module DPS Visio, Module DPS+, Module MVP, Module MVP+ Orchestra®) on the Base Intensive

We recommend you partially or completely recharge the battery when you receive the devices or in the case of prolonged storage so as to prevent all risk of premature discharge.

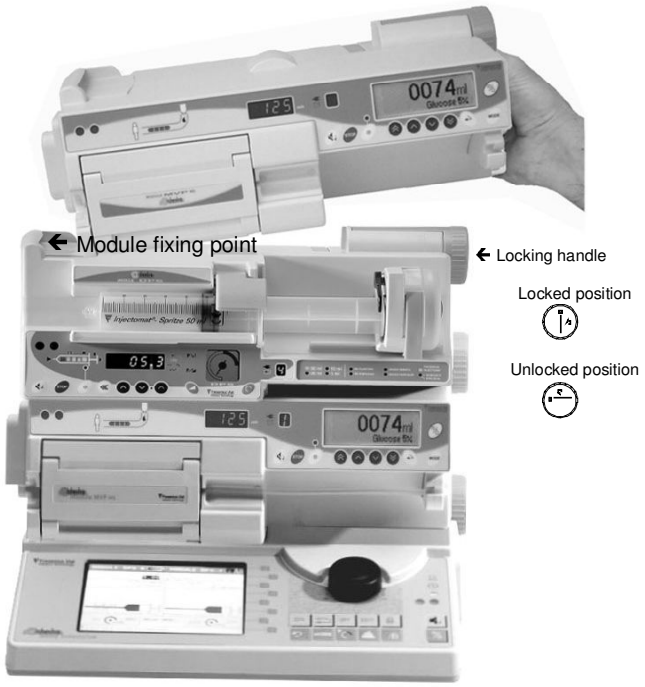
Special attention must be paid to the stability of the **Base Intensive** when several Modules are used.

From the 4th **Module** onwards, the **Base** must be equipped with a **Multifix** to ensure rigidity (see « accessories » page 21).

The **Base Intensive** can be used on mains or battery (red indication because looks like an alarm, normal functioning of Base Intensive is on mains).

Note: connect device to mains as soon as possible to recharge Base and Modules' batteries.

1. Connect the power supply cord to the **Base Intensive** and to the mains source. The mains power indicator lights up.
2. Install the Modules on the **Base Intensive** or on another **Module** already installed and turn the locking handle to locked position.



Ex. : Module DPS and Module MVP

3. Quick check: see protocol page 14. This test is recommended before use or when the device has not been used for a long time. This test allows a complete alarms and safety features check.

Use of keyboard and rotary knob

Parameter selection and modification

Parameter selections and modifications are done with the rotary knob and the keyboard selection keys.

- To move from an item to another, use the rotary knob.
- To select an item, press the rotary knob or the ENTER key.
- To modify a value of the selected item, use the rotary knob.
- To confirm the modification, press the rotary knob or the ENTER key.

Symbols	Parameter selection and modification
OK	Confirm parameters and go to next screen.
EXIT	Exit from an item or a screen without saving the modifications.
ENTER	Confirm a selection or a value under modification.
	Base Intensive power on and off.

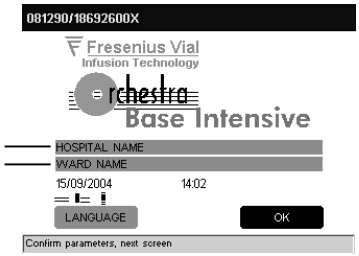
Other functions

Symbols	Other available functions
MODE	Selection of particular **Module DPS** infusion modes functions.
	Access to the 2 channel relay program with **Module DPS**.
	Access to infusion pressure information and authorized parameters adjustment.
	Allows locking of **Base Intensive** keyboard.
	Access to history data.
OPT	Access to OPTIONS menu.
	Access to the visualisation of drug library parameters.
	Silence alarm.

Welcome screen

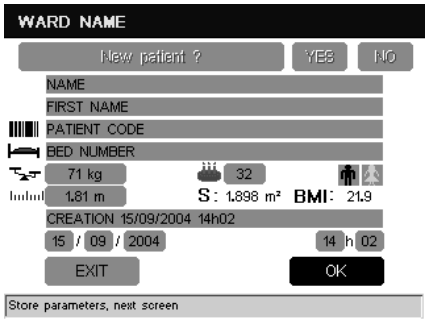
When **Base Intensive** is put into use for the first time, complete the following items:

Free items.
Ex.: Hospital, department



If necessary, select language with the rotary knob.

Patient screen



Note: It is recommended to use codes to identify the patient since the **Base Intensive** memorizes the patient infusion history. This allows to guarantee patient anonymity according to the law in force.

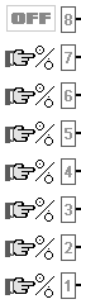
Symbols	Function
	Patient code Patient identification with a 30 characters code.
	Bed/room number Bed/room identification with a 30 characters code.
	Patient weight The weight must be entered when you select a new patient. **This value is used when flow rate units and volume are calculated by weight.** ▪ From 250 **g** to 1 **kg,** 10 **g** increment. ▪ From 1 to 10 **kg,** 100 **g** increment. ▪ From 10 to 250 **kg,** 1 **kg** increment.
	Patient age Adjustment from 1 to 24 **months,** 1 **month** increment Adjustment from 2 to 150 **years,** 1 **year** increment**.**
	Patient sex **Male** **Female**
	Patient's height: from 0,20 to 2,50 **m,** 1 **cm** increment.
S	Calculated body surface.
BMI	**B**ody **M**ass **I**ndex.

Note: the hour and date adjustment is possible only when you select a new patient (ex: summer or winter time change).

Module DPS switching on

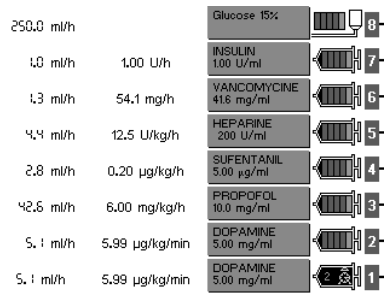
When **Base Intensive** is connected to the mains, **Module DPS** can be switched on from their own respective keyboards by pressing the key or from the **Base Intensive** by pressing the key.

When **Base Intensive** is working on its battery, **Module DPS** can be switched on only from their own keyboards by pressing the key.



Symbols	Module DPS Orchestra® switching on conditions
	Module can be switched on from the Base Intensive Orchestra® or from its keyboard when the Base Intensive is connected to the mains.
OFF	Module can be switched on only from its own keyboard when the Base Intensive is connected to the mains.

Summary screen



When a **Module** is switched on without any drug program, the message DRUG ? is displayed. This message means that no drugs have been programmed via the **Base Intensive** or that this drug is not identified at the new connection.

Symbols	Modules type
	Module DPS
	Module MVP

Symbols	Modules status
	Infusion
	Pause
	Alarm
	Module DPS awaiting for a 2 channel relay (See page 8)

Drug programming and infusion start

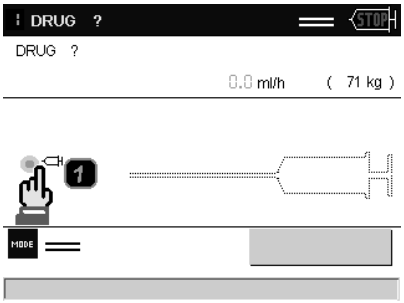
To program a drug:

1. Select the channel number with the keys.
2. Select or confirm the installed syringe.
3. Select or confirm the drug.
4. Adjust infusion parameters.
5. Start the infusion.

Note : in order to improve infusion start, it is recommended to prime the infusion line until a drip appears.

Syringe selection

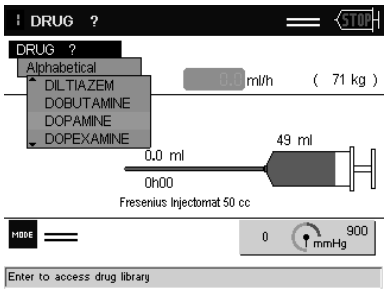
To reach the syringe programming screen:



1. Install a syringe.
2. Select and confirm syringe on the **Module DPS** (Please refer to the Module DPS Operator's Guide, page 2).

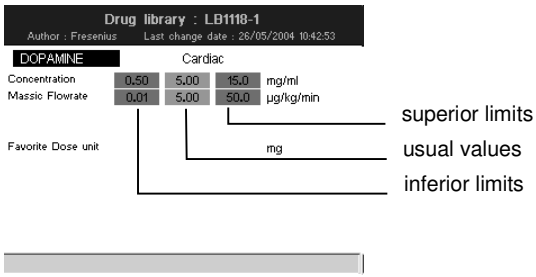
Note: The flashing symbol reminds the user that syringe selection and confirmation must be done from the **Module DPS** keyboard.

Drug programming



1. Selecting the drug enables access to the programmed drug library.
2. Select the drug name from the alphabetical list or from the family name.

It is possible, at any time, to recall the drug preprogrammed values from the library pressing the key.



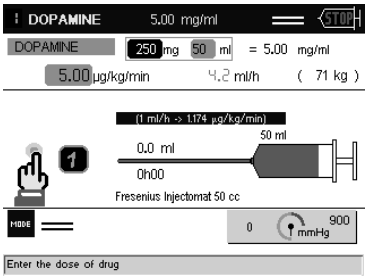
Important:

The Base Intensive integrates a drug library as example. Prior to any use, the authorized personnel must check that usual drug values correspond to the protocols used.

Prior to any use of the Base Intensive, it is necessary to carefully read Drug'Lib Operator's Guide to modify or confirm the drugs parameters.

Parameters adjustment and infusion start

Values indicated per default are the usual values defined in the drug library.



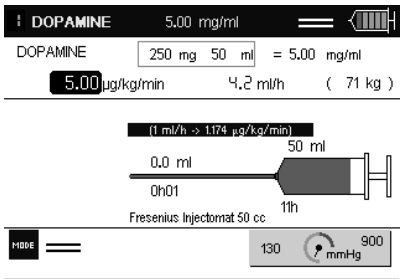
1. Check that the drug name is the one contained in the syringe of the selected channel.
2. Confirm or adjust, if necessary, the drug dilution value contained in the syringe.
3. Confirm or adjust, if necessary, the dose rate value according to the desired administration.
4. Start infusion pressing the key of the **Module DPS**.

Note: The symbol and START displayed alternatively reminds the user that infusion start is made pressing the key of the **Module DPS**.

Flow rate modifications and information during infusion

The infusion rate, in the selected unit, can be modified from the **Base Intensive**.

Rate (in ml/h) can be modified from the Module keyboard. Information about rate is automatically updated on **Base Intensive**.



Flow rate program

To modify the infusion rate from the **Base Intensive** :

1. Select the channel pressing the key.
2. Press the ENTER key or the rotary knob.
3. Adjust flow rate value with the rotary knob.
4. Press the ENTER key or the rotary knob to confirm the modification.
5. Press the Module's key to confirm the new flow rate has been done.

During a rate modification on the **Base Intensive**, pressing the EXIT key will revert back to the initial value.

Notes:

At syringe change:

- the name and concentration of the last selected drug are proposed per default,
- if the selected drug name is not modified, then the total infused volume is cumulated in the programming screen of the selected channel.

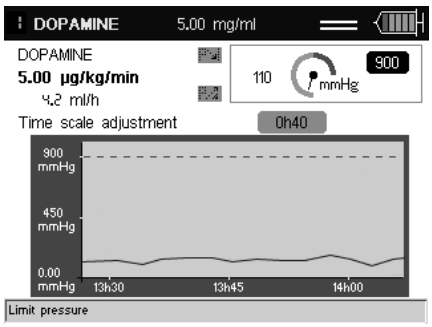
Infusion pressure adjustment and display

Pressure limit value programming and drops in pressure activation are made directly from the **Base Intensive** for a **Module DPS** only.

For the use of these functions on the **Modules**, please refer to the **Module** Operator's Guides.

To adjust pressure parameters from the **Base Intensive**:

1. Select the channel pressing the key.
2. Press the key to have access to the adjustment screen:



Limit pressure

It is also possible to modify the pressure alarm threshold, either in 3 pre-set threshold mode or one variable threshold mode depending on the **Module DPS** configuration.

Infusion stop

To stop infusion, press the STOP key from the Module.

Turning off the Modules

When no Module is infusing, turning off the Modules can be done by pressing the % key from the **Base Intensive** or by pressing the % key from the **Module**.

When a Module is infusing on the **Base Intensive**, turning off the Modules is done by pressing the % key from the **Module** for more than 2 seconds.

Turning off the Base Intensive

Turning off the **Base Intensive** is done by pressing the % key. Some information messages may be displayed when turning off.

Infusion modes

Continuous mode

Continuous mode is the default mode run by the Base Intensive.

Bolus mode

Bolus programming and activation are possible when a channel is in continuous infusion or after the injection of a loading dose.

1. Select the channel pressing the key.
2. Press the key to have access to the Modes selection screen.
3. Select the Bolus mode .
4. Adjust the bolus dose value to be infused as well as the duration. The volume to be infused as well as the infusion flow rate (in ml/h) of the **Module DPS** are automatically recalculated.
5. Check bolus parameters.
6. Start bolus infusion selecting the START icon and confirm on the **Module DPS**. In case of a pre-program, select the STORE icon to confirm parameters storage.

When bolus has been delivered, the **Module DPS** returns to its initial status (stop or infusion), bolus programming parameters are stored when there is a new programming.

Loading dose + continuous mode

Loading dose programming and starting followed by a continuous flow rate are possible after a drug selection and before starting the infusion.

1. Select the channel and the drug.
2. Press the key to have access to the Modes selection screen.
3. Select the Loading dose + Continuous Mode .
4. Adjust the loading dose value as well as its duration. The **Module DPS** volume to be infused and infusion flow rate (in ml/h) are automatically recalculated.
5. Adjust the maintenance flow rate value.
6. Start the loading dose infusion selecting the START icon. You can stop the loading dose infusion, at any time, pressing the STOP key of the **Module DPS** or with the STOP icon of the **Base Intensive**. It can be reused selecting the START icon.

At the end of the loading dose infusion, the **Module DPS** infuses at the programmed maintenance flow rate.

In case you use a drug that does not require any administration adjustment (if minimum dilution is the same as the maximum dilution and the typical dilution), the **Base Intensive** displays automatically the loading dose screen.

Note: Access to CONTINUOUS, BOLUS, LOADING DOSE + CONTINUOUS modes can be locked or unlocked by user with a code to be accessed from the summary screen.

Two channel relay

The use of the 2 channel relay is particularly recommended to avoid any infusion discontinuity, for example, in case of infusion of cardio-vascular or short half-life anaesthetic drugs.

Principle

The 2 channel relay consists in associating two channels that will infuse, either one after the other a same drug at the same administration.

In case of different concentrations for the same drug, the flow rate (in ml/h) calculation will be done automatically to respect the prescribed dose.

Installation of the two syringes can be done simultaneously only if the syringe of the second channel in relay has been validated after the activation of the 2 channel relay.

Pressing the PRIME/BOLUS key is mandatory for the channel in relay so as to improve the two channel relay performances.

In case the second syringe is installed later, the user will preprogram a prealarm « relay not ready » to be informed from 5 minutes to 1 hour before the end of infusion of the first syringe in order to complete the relay.

Recommendations to operate a 2 channel relay

The respect of these recommendations is mandatory when infusing hemodynamically unstable patients.

Orchestra® Infusion Workstation installation

- Place Base Intensive at the same level or lower than the patient.
- Use Module DPS from position 1 to position 6 only.

Syringes to be used

- Adapt syringe size to the selected flow rate:

  flow rate < 0.5 ml/h : 5 and 10 cc syringes,

  0.5 ml/h < flow rate < 1 ml/h : 5, 10 and 20 cc syringes,

  flow rate > 1 ml/h : any syringe size, i.e. 5, 10, 20, 50/60 cc.
- Please refer to Module DPS syringe list.

2-channel relay syringe installation

- Up to 24 hours before the infusion starts.
- Always check that the selected syringe corresponds to the installed syringe.
- Make sure that the infusion line is not connected to the patient when priming.
- Prime till a drop appears at the end of the infusion line.

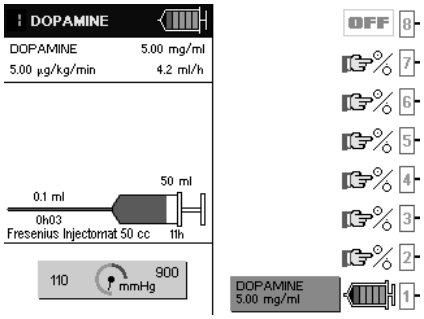
Patient connection

- Use catheters with low priming volume and reduced compliance.
- Unidirectional valves are authorised while anti-siphon valves are not (the open pressure can generate infusion delay).

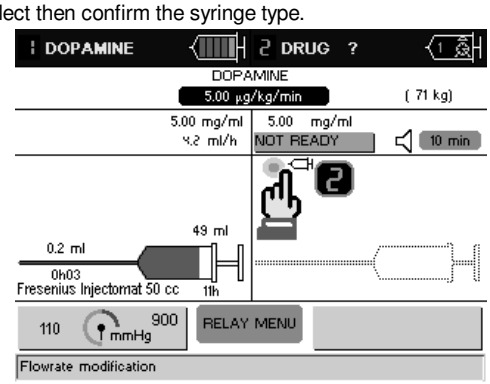
Carefully respect the cautions applying to continuous infusion of vaso-active drugs (dedicated access route, avoid discontinuous injection, …).

Two channel relay program

1. Program a drug from the library on a channel. Adjust, if necessary, the infusion parameters and start infusion.
2. Press the key to reach the screen for selection of the channel to be associated.

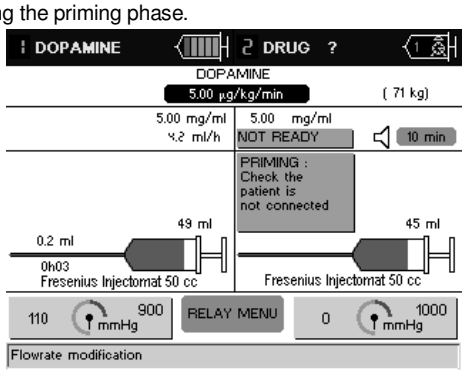


3. Power on the channel to be associated :
   - either from the **Base Intensive** with the key.
   - or directly on the **Module DPS** and select the number of the channel to be associated with the key.
4. Syringe installation on the channel relay:
   a. Install the syringe containing the same drug as the one programmed during the relay.
   b. Select then confirm the syringe type.

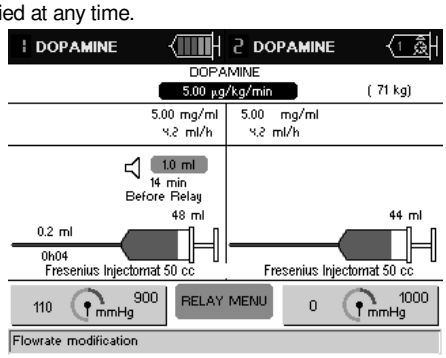


   c. "PRIME - Check patient is not connected to the syringe" message displays on the **Base Intensive**. On the **Module DPS**, the PR INE message displays alternatively with the drug name .

   Press the PRIME/BOLUS key of the **Module DPS** to be in prime mode (PR INE message displays on the **Module DPS**). Press a second time and maintain pressed the PRIME/BOLUS key to make the purge. **Prime till a drop appears at the end of the infusion line**.
   Important: make sure that the patient is not connected to the syringe during the priming phase.



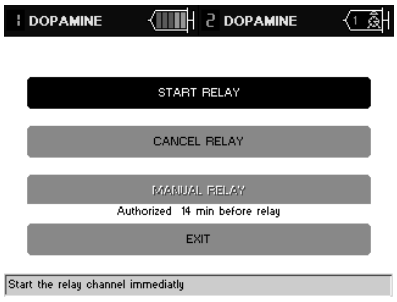
   d. Confirm the drug name pressing the key of the **Module DPS**. If necessary, adjust concentration.
   e. At the end of the 2-channel relay program, the **Module DPS** displays the drug name alternatively with the RELAY message. Once the 2-channel relay is programmed, the flow rate may be modified at any time.



The 2 channel relay is now set.
Prealarm will occur at set time to warn of imminent relay.
Relay will occur automatically.

Two channel relay menu

By activating this field with the rotary knob, you have access to this menu. The following screen displays:



START RELAY

By activating this field with the rotary knob, you start the channel relay and simultaneously the first channel stops.

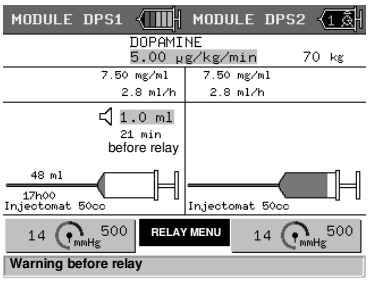
CANCEL RELAY

This function allows to cancel the relay mode for the channel in relay.

ACCESS TO MANUAL RELAY

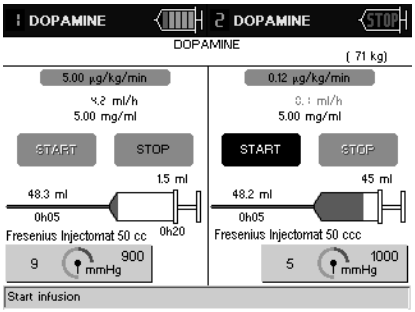
By using this function, you command simultaneously the two channels in relay. You have access to this function only when the warning before relay has been selected.

Example:



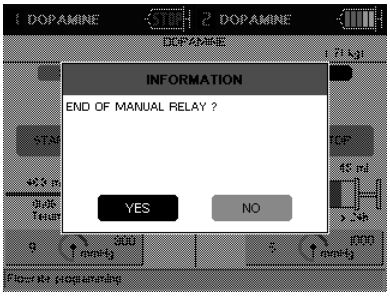
In this example, the manual relay is authorized with a « warning before relay » at 1.0 ml before the end of infusion, that is to say 21 minutes before the relay at a flow rate of 2.8 ml/h.

Activating the manual relay from the rotary knob, the following screen displays:



From the **Base Intensive** keyboard, user decides: to start, to stop or to set the flow rate for each two channels in relay.

The manual relay switching off is made stopping one of the two channels and pressing the EXIT key. The following screen is displayed:



Select YES with the rotary knob.

History

Base Intensive stores, in real time, infusion data during 96 hours. During this period, user can:

- define an observation window from 1 to 96 hours, with one hour increment,
- choose the date and hour of this observation window.

Data are updated each ten seconds or each time you use the function.

Access to different information regarding doses, infused volumes and flow rates of each drug as well as the fluid balance display allow, if you think it is necessary (for example during personnel turnover), to rapidly know the main information about the infusions administered to the patient.

Notes: If several Modules (example: 2 channel relay) infuse the same drug, the **Base Intensive will automatically update the drug history**.

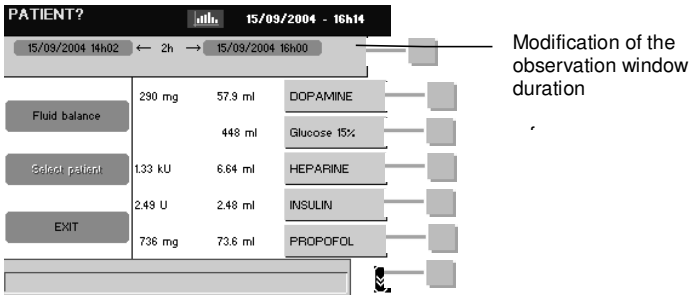
According to the patient treatment duration and the number of Modules installed on the **Base Intensive,** it may be possible to have access to the last 4 patients history (if no infusions are running).

Pressing the key, you have access to the selection menu of the different histories.

Please note that when one or several Modules are disconnected from the **Base Intensive** while they were previously programmed, their history log will be restored when they are reconnected to the **Base Intensive**.

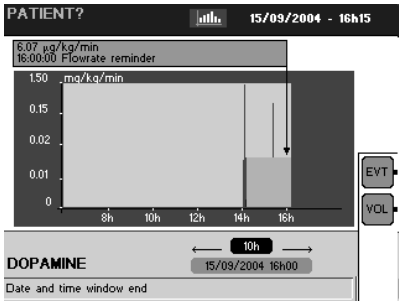
Access to history data

When you press the key, you have access to the summary screen for volumes and doses infused per drug in the selected period.



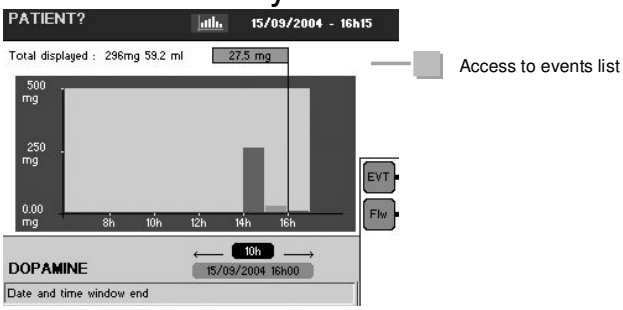
Pressing the keys gives access to information dedicated to each drug:

Cumulated doses and volumes history

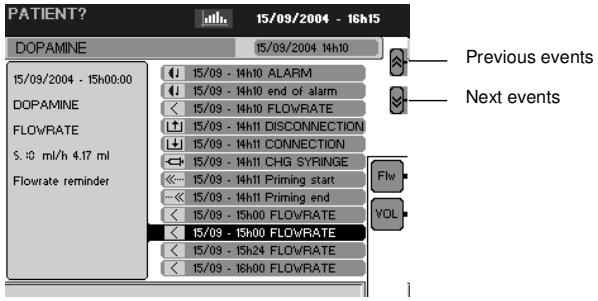


Each segment represents 1 hour. The value displayed on the last segment is the one of the observation time.

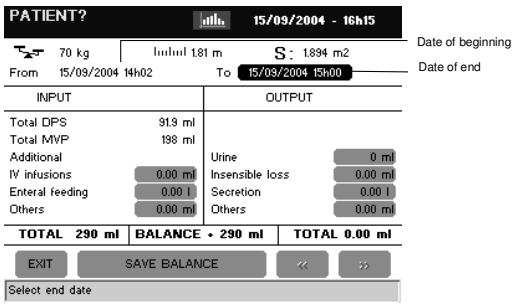
Flow rates history



Horodated events list



From the summary screen for infused volumes and doses, activating the « fluid balance » option gives access to the summary screen for inputs and outputs.



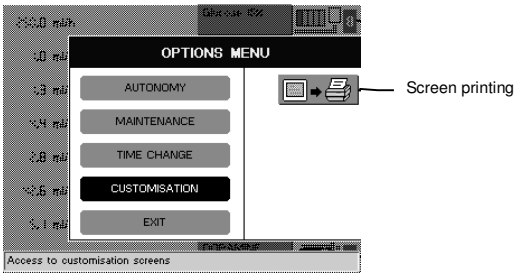
It is possible to store 24 balances (ex.: memorisation of a balance every 4 hours during 96 hours).

The fluid balance storage allows resetting the dose and infusing volume values per drug. It is then possible to evaluate the quantities of infused drugs on periods of time corresponding to fluid balance period.

Note : the hour of beginning and hour of end of liquid balance must be entire (ex. : 16 h 00).

OPTIONS menu

Press the OPT key to have access to the following display:



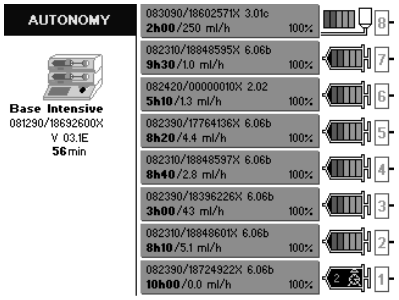
The options from this screen give access to the following information:

- **autonomy,**
- **maintenance,**
- **time change,**
- **customisation,**
- **screen printing,**
- **detailed printing.**

AUTONOMY menu

This field gives access to the Modules and **Base Intensive** battery autonomy.

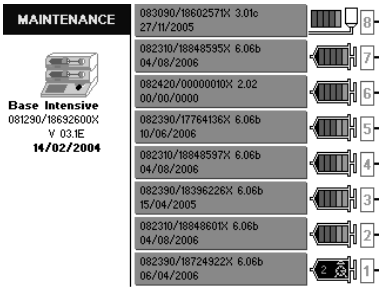
Example:



MAINTENANCE menu

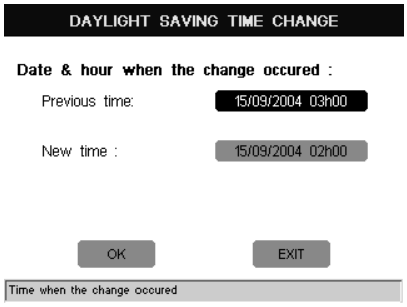
This field gives access to the serial numbers and next maintenance dates for Modules and **Base Intensive**.

Example:



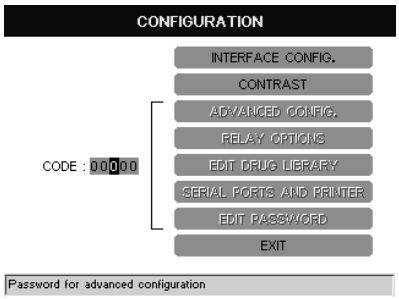
TIME CHANGE menu

This field gives access to the daylight change. Example:



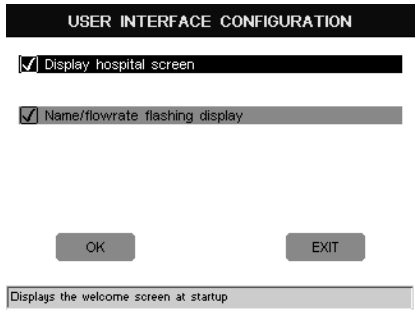
CUSTOMISATION menu

This field gives access to the customisation of the **Base Intensive** different configurations:



INTERFACE CONFIGURATION:

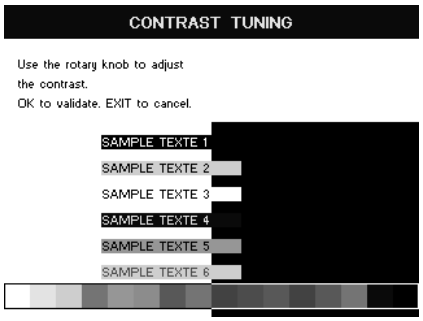
This field gives access to:



This option allows to define the **Base Intensive** first welcome screen and to display the flow rate alternating with the drug name on the **Module DPS**.

CONTRAST:

This field gives access to:

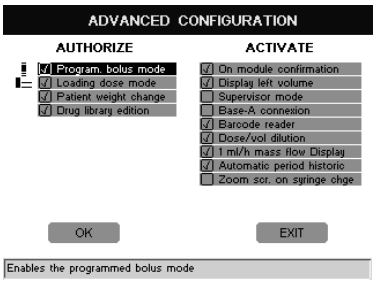


This option allows to tune the contrast of the **Base Intensive** screen.

ADVANCED CONFIGURATION:

This option is protected. You only have access to this menu after entering the 00123 code with the rotary knob. If necessary, consult our Maintenance Service for the code modification.

According to your department practice, this field gives access to:



Programmed bolus mode authorized

Activation/disactivation of the programmed bolus function.

Loading dose mode authorized

Activation/disactivation of the loading dose mode function.

On Module confirmation

If this function is disactivated, any flow rate changes validation will be done pressing the **Base Intensive** rotary knob.

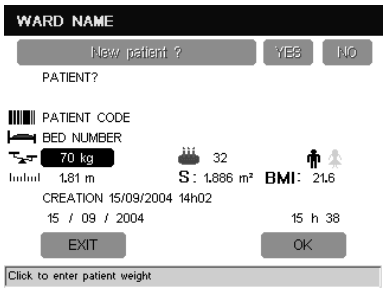
Patient weight change authorized

For specific administration protocols, the physician may have to take into account the patient weight variations to adjust, either infused flow rates (ml/h), or the administration depending on the new weight setup (example: µg/kg/min) without stopping the infusion.

This function concern only drugs selected from the **Base Intensive** with an administration that takes into account the patient's weight.

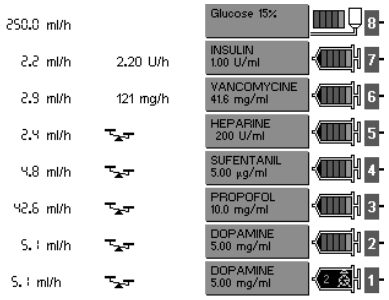
How to change the patient weight during the infusion:

1. Return to the « patient identification » display:



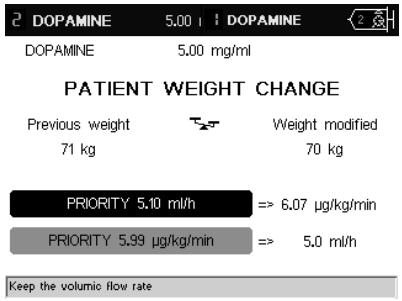
2. Change patient weight with the rotary knob.

3. Confirm pressing the OK key. The following screen is displayed:



4. Select the channel(s) where the weight must be modified pressing the key of each channel. This (these) channel(s) is(are) identified with symbol.

The following screen is displayed:



In this example, the « priority 5.10 ml/h » field activation will generate the recalculation of the mass rate necessary to respect the current flow rate in ml/h. the « priority 5.99 µg/kg/min » field activation will generate the recalculation of the flow rate necessary to respect the current mass rate in µg/kg/min.

Display left volume and time

Activation/disactivation of display of the volume to be infused and time.

Supervisor mode

Unique visualisation of the summary screen.

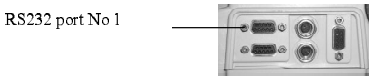
Enable Base A connexion

This function allows to connect one **Base A** to one **Base Intensive** and to monitor up to 8 additionnal Modules. To go from the **Base Intensive** summary screen to the one of the **Base A,** press the OK key.

Drugs infused from **Base A** are integrated into **Base Intensive** history.

Note : **Module** flow rate adjustment from **Base A** is performed directly on the **Module**.

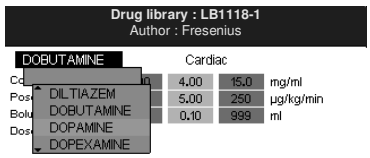
Connection of **Base A** to **Base Intensive** is performed through RS232 port No 1 using the adequate RS232 cable.



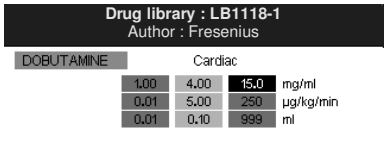
Drug library edition authorized

It is possible to modify drug library directly from the **Base Intensive** to modify the adjustment range.

1 – Drug selection :



2 – Different items modification



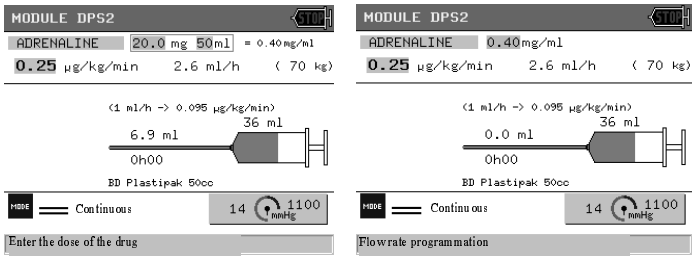
Note that the access to this function is possible only if no patient is selected and if the infusions are stopped.

Enable barcode reader

The selection of the drug name and administration can be done directly from labels stuck on the syringe and with a barcode reader. The labels printing is made from the **Drug'Bar** software. Please refer to this software operator's guide.

Enable dilution according to dose/volume

This function allows to fill in the dilution indicating the drug dose and the administration volume.



Activated option Disactivated option

Enable display mass flow for 1 ml/h

This function allows to display, in the drug program screen, the correspondance between a 1 ml/h flow rate and the corresponding mass rate in chosen unit.

Automatic period history

This function allows to display automatically the doses and volumes infused during predefined times (4h, 8h, 12h and 24h) since the hour of the last fluid balance memorisation.

Example : case of a balance every 8 hours.

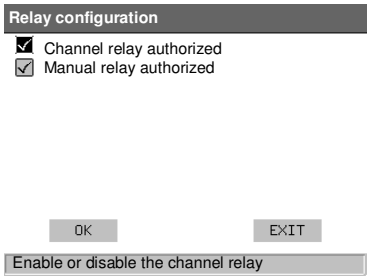
The fluid balance is stored at 8 h 00.

The history reading is done at 16 h 30 : doses and volumes displayed correspond to doses and volumes infused from 8 h 00 to 16 h 00.

RELAY OPTIONS:

This option is protected and accessible only after the 00123 code has been entered with the rotary knob.

According to your department practices, this one allows you to activate or disactivate the hereunder functions:



The PRINTING menu

This menu allows the detailed or summarised print out of the history data:

- **Doses,**
- **Total volumes/1 hour,**
- **Flow rate graphs,**
- **Drugs list.**

It is also possible to print the drug parameters of the library.

The choice of data to be printed is done according to the screen you are consulting.

The printer is connected to the isolated serial port identified by the symbol.

According to the **Base Intensive** versions, you can have access to these options or not.

Safety features

The Base Intensive has a continuous inspection system which functions as soon as the pump is in use.

Any internal failure or anomaly detected will be immediately displayed. Nevertheless, the qualified personnel in your establishment or our After-Sales Department should always be notified of any abnormal function where no specific cause can be found.

Connection / disconnection

The flow rate value limits of the drug selected in the library are stored when the **Module** is disconnected from its **Base**. It is impossible to program a flow rate out of the drug limits.

When you change a syringe on a disconnected **Module**, the default drug name is the one previously used. Please make sure that the drug concentration in the new syringe is the same as the previous one before confirming the drug name and its concentration.

If the drug name or concentration is different, select « **NO** » at the drug selection. The programmed limits for the previous drug are cancelled.

Alarms, pre-alarms and warnings

All **Base Intensive** alarms, pre-alarms and warnings are displayed and/or are indicated with an audible signal:

- Mains disconnection pre-alarm.
- Low battery pre-alarm and alarm.
- Burned 2 channel relay pre-alarm.

When you press the **Base Intensive** SILENCE ALARM key , the message is recalled.

Quick check protocol

This test is mandatory when the pump is used in anaesthesia.

It allows a complete alarm and safety features check of the Base Intensive (no patient connected).

Serial numbers (ID/N): Base Intensive: _____ Module: _____

Date: _____ / _____ / _____Section: _____ Name: _____

	Results OK
1. Power supply lead not connected, install at least one **Module** on **Base Intensive.** Then, switch the **Base** on pressing the key. Check that battery indicator illuminates and the information screen displays.	YES ☐ NO ☐
2. Check indicators' functionality during auto-test.	YES ☐ NO ☐
3. Check audible alarms work.	YES ☐ NO ☐
4. Check LCD integrality.	YES ☐ NO ☐
5. Connect the device to the mains source, check mains indicator illuminates.	YES ☐ NO ☐
6. Switch the first **Module** on and check its position number on the summary screen.	YES ☐ NO ☐
Note: quick check is OK if answers are "yes" for all items.	YES ☐ NO ☐

For the Orchestra® Module's quick check, please refer to their Operator's Guides.

Base Intensive - Performances

This Operator's Guide describes the programming of a Module DPS from the Base Intensive. For the use of functions available from the Module's keyboard, please refer to its Operator's Guide.

Flow rate range available from the Base Intensive keyboard for a Module DPS

- From 0.1 to 1200 ml/h, 0.1 ml/h increment.

Time limit programmable for the loading dose and the bolus

- From 1 second to 60 minutes, 1 second increment.

Volume limit programmable for the loading dose and the bolus

- From 1 ml to 65 ml, 0.1 ml increment.

Flow rate accuracy

Please refer to the **Modules** Operator's guides.

Volume variations during the relay setup:

Syringe types	Volumes variations		Average setup time (in seconds)
	Δ V average (in ml)	Δ V maxi. (in ml)	
50 cc	0.100	0.200	125"
20 cc	0.040	0.130	72"
10 cc	0.016	0.034	45"
5 cc	0.018	0.030	34"

Minimum volume is lower than – 0.02 ml, whatever the selected syringe type.

These values are equivalent to volume variations observed for a simple connection of an IV infusion line on the patient.

Units and conversion formula

Programmable dilution units are in mg/ml, µg/ml, ng/ml, U/ml, kU/ml, mg, µg, ng, g, U, kU, mol, mmol, Cal, kCal.

Mass rate units are calculated from mass units (ng, µg, mg, g) or Insulin (U, kU) or mol, mmol or cal/kcal per time unit (24 h, h, min) pondered or not by patient's weight (kg).

Bolus dose or initial dose are calculated from mass units (ng, µg, mg, g) or Insulin (U, kU) or mol, mmol or cal/kcal pondered or not by patient's weight (kg) or in ml.

The used formulas are:

- **Q = D*P/C with pondered weight,**
  Q = D/C without pondered weight.
- **V = d*P/C if dosis is pondered by weight,**
  V = d/C if dosis is not pondered by weight.

Q: Volumic rate, in ml, pondered by time unit (24h, h, min)

V: Bolus volume de bolus, in ml.

D: Mass rate.

d : Bolus dose.

C : Drug concentration.

- **$S = (p^{0.425} \times T^{0.725}) * 0.007184$ unit in m^2**

S : Calculated body surface of the patient,

P : Weight in kg,

T : Height in cm or m/100.

- **BMI (Body Mass Index) = P / T^2**

P : Weight in kg,

T : Height in m.

Adjustment range, accuracy, displayed values

Dose rate and concentration adjustment range:

- Inferior to 1: 0,01 increment.
- Between 1 and 10: 0,05 increment.
- Between 10 and 100: 0,5 increment.
- Between 100 and 1000: 5 increment.
- Superior to 1000: 50 increment.

Flow rate is calculated according to formula and units described in paragraph « Units and conversion formula ».

The flow rate order sent to the **Module DPS** are rounded off and taken into account at 1/1000 of ml/h. The flow rate value displayed on the **Base** and on the **Module** is at 1/10 of ml/h.

Base Intensive – Technical characteristics

External power supply

Voltage	From 95 to 240 Vac
Frequency	50/60 Hz
Max. consumption	1500 mA
Max. power consumption	125 VA
Protective fuse	T 1600 mA 250 V IEC 127
Output voltage	7.35 V (mini 7.15 V)
Output current	7 A

Battery

Characteristics	6 V 1,2 to 1,3 Ah - Sealed lead battery
Battery life	min. 1 hour
Battery recharging	Partial (70% of capacity): 8 hours Total (100% of capacity): 16 hours

Compliance

Complies with Medical Device Directive 93/42 EEC:
CE mark: **CE 0459**

Safety of Medical Electrical Equipment:
Complies with EN/IEC 60601-1 and EN/IEC 60601-2-24

IP34	Protection against splashing fluid
	Protection against leakage current: Type CF equipment
	Protection against electric shocks: Class II equipment

Electromagnetic Compatibility:
Complies with EN/IEC 60601-1-2 (second edition) and EN/IEC 60601-2-24. Detailed information is given in paragraph Guidance and manufacturer's declaration on electromagnetic environment.

Emission compliance:
- Radiated and Conducted RF: CISPR 11/EN 55011, Group 1 Class B
- Harmonics: EN/IEC 61000-3-2, Class A
- Voltage Fluctuations / Flickers: EN/IEC 61000-3-3

Immunity compliance:
- Electrostatic Discharges (ESD): EN/IEC 61000-4-2
- Fast Transient / Burst: EN/IEC 61000-4-4
- Surges: EN/IEC 61000-4-5
- Voltage dips, variations: EN/IEC 61000-4-11
- Magnetic Field: EN/IEC 61000-4-8
- Conducted RF: EN/IEC 61000-4-6
- Radiated RF: EN/IEC 61000-4-3

Device materials

Lower case:	Polycarbonate with glass fiber
Upper case:	ABS
Locking bloc:	Polycarbonate with glass fiber
Labels	Polyester
LCD glass	PMMA

Dimensions - Weight

Dimensions	Width 32 cm / Depth 30 cm / Height 7.5 cm
Weight	approx. 2.6 Kg

Indicators lights

Mains power operation		Yellow
Mains disconnection alarm		Flashing red
Pre-alarm		Orange
Alarm		Red
LCD screen		¼ VGA color

Symbols

	Direct current
	Input voltage signal
	Output voltage signal
	Battery
	Fuse
	Functional earth
	Patient's hand set (not used)
4000 V **RS 232**	RS 232 connection insulated 4000 V
RS 232-1	Additional RS232 connection n°1 To connect one Base A or a device conform to the IEC 601.1 Standard.
RS 232-2	Additional RS232 connection n°2 To connect the bar code reader. 5 V voltage.
	Nurse call connection

To use the 3 RS232 and the nurse call connections, please refer to the corresponding technical file to respect connections.

Precautions to be taken

The symbol ⚠ visible on the condensed instruction guide of the devices recommends this Operator Guide should be completely read, in accordance with the EN 60 601-1 standard.

***Fresenius Vial* will not be liable for any damages or claims, medical or otherwise, of any nature whatsoever, whether direct or consequential, caused by improper use of this device.**

Special attention must be paid to the stability of Orchestra® when several modules are used on **Base Intensive**.

From the 4th Module onwards, Orchestra® must be equipped with the Multifix accessory to ensure rigidity.

During transportation of **Orchestra®** with **Multifix** accessory, only install maximum 6 **Modules** on **Base Intensive**.

Use the device in horizontal position, on a table, or with the ***Multifix*** for use on a pole.

Fresenius Vial recommends not to place the Modules higher than 1,3 meter above patient.

We recommend you partially or completely recharge the battery when you receive the devices or in the case of prolonged storage so as to prevent all risk of premature discharge.

To preserve the environment, remove the battery from the device prior to destruction or at the end of the device life and as during normal maintenance replacement, return it to a competent recycling organisation. Proceed in the same way for the device itself (electronic boards, plastics…).

Avoid short circuit and excessive temperature.

Anaesthetic substances: the device must not be used in the presence of inflammable anaesthetic agents due to the risk of explosion. It should always be used away from all risk areas.

Use only disposable proposed in the **Module DPS** and **Module MVP** Operator's Guide in accordance with local standard operating procedures and good clinical practices. Using NO recommended disposable could lead to serious hazards such as free flow or pump degradation.

Fuses should be replaced by equivalent parts. This should be done by a qualified technician. Refer to the part list of the technical manual for full specification.

The **Base Intensive** may only be connected to the mains with the power cord supplied by the manufacturer. Check that the supply voltage corresponds with the value indicated on the label placed underneath the device.

Do not exceed the permitted voltage whether the supply is from the mains, an external source or via the different external connections.

Standard precautions should be taken to prevent contamination or injuries while discarding the associate disposable (e.g.: syringes, extension sets, needles, etc.).

Only use Luer Lock connection to prevent disconnection due to infusion pressure.

Check that all equipment connected to **Orchestra®** resist to a pressure of 2000 HPa.

Do not use in conjunction with positive pressure infusion devices that could generate back pressure higher than 1 500 Hpa susceptible to damage infusion disposable and the device.

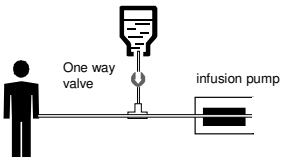
While in use, negative pressure variation may occur in the syringe, by the relative height from the device to the injection site or by combined infusion devices such as blood pump, alternative clamp, etc.

Pressure variation may generate flow discontinuity mainly noticeable at low flow rates.

When the container is placed higher than the injection site, please pay attention to correctly manipulate the infusion set only when the extension set is clamped or disconnected from patient side.

Make sure that infusion line does not hinder moving parts of other devices.

Fresenius Vial recommends the use of one way valves or positive pressure infusion devices for multi-line infusions. If there is no one way valve on a gravity infusion line during a multi-line infusion, this will make it impossible to detect occlusions on the patient side, and could result in accumulation of the drug being infused in the gravity line, which could later be infused in an uncontrolled manner when the occlusion is released. Place the connection between the gravity line and the pump-driver line as near to the start of the set as possible in order to minimise the dead space and consequently the impact of any change in flow rate on the gravity line.



For « Y » connections used in 2 channel relay, it is recommended to prime the lines particularly in case of concentration changes where dead volumes of the sets may generate a risk of under or over dosage.

This device can be disturbed by environmental pressure or pressure variations, mechanical shocks, heat ignition sources, etc...

A non-medical electric device connected to the RS232 interface must be in conformity with the suitable IEC/EN standard (e.g. IEC / EN 60950). In all cases, the IEC/EN 60601-1-1 international standard must be taken into account. Both installation and use of Base Intensive via an RS 232 link must comply with the accompanying document*: RS 232 protocol for Base Intensive*. This document is available from our After-Sales Department.

Fresenius Vial will not be responsible whatsoever for use of any interface communication between the Base Intensive and computer system.

Opening the pump must only be carried out by the qualified personnel in your establishment, and taking all the necessary technical precautions. We recommend you follow the maintenance procedures defined in the Technical Manual. To obtain a copy of this document, please contact our After-Sales Department, specifying the identification number of the device. Non-respect of these procedures is dangerous to the personnel and may damage the pump.

Guidance and manufacturer's declaration on electromagnetic environment

The **Base Intensive** has been tested and found to comply with the applicable standards for electromagnetic Compatibility for Medical Devices. These standards are designed to provide adequate *immunity* to prevent undesirable operation of the **Base Intensive**, as well as a limitation of *emissions* from the device that may cause undesirable interference to other equipment.

If the **Base Intensive** is operating in the vicinity of other equipment which causes high levels of interference (e.g. HF surgical equipment, X-rays equipment, nuclear spin tomography units, mobile telephones, wireless access points, etc...), maintain the recommended protective distances (see Table 206), re-orienting or re-locating the **Base Intensive**.

The following tables specify the suitable electromagnetic environment for using the device and provide guidance to assure that it is used in such an environment.

Guidance and manufacturer's declaration – electromagnetic emissions TABLE 201

The **Base Intensive** is intended for use in the electromagnetic environment specified below. The user of **Base Intensive** should make sure it is used in such an environment.

Emissions test	Compliance obtained by the device	Electromagnetic environment - guidance
RF emissions CISPR 11	**Group 1**	The **Base Intensive** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	**Class B**	The **Base Intensive** is suitable for use in all establishments, including domestic and hospital establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	**Complies Class A**	The **Base Intensive** complies by default with Harmonic emissions because input power is lower than the minimum input power specified in the IEC 61000-3-2.
Voltage fluctuations Flicker emissions IEC 61000-3-3	**Not applicable**	Voltage fluctuations / flicker emission are not applicable, because the **Base Intensive** cannot generate a significant voltage fluctuations and flicker emissions according to IEC 61000-3-3.

Guidance and manufacturer's declaration – electromagnetic immunity TABLE 202

The **Base Intensive** is intended for use in the electromagnetic environment specified below. The user of **Base Intensive** should make sure it is used in such an environment.

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8kV contact ± 15 kV air	Coatings of the floors out of wooden, tilings, and concrete, with a relative humidity level at least 30 %, makes it possible to guarantee the level of necessary conformity. If it is not possible to guarantee this environment, of the additional precautions must be taken, such as: anti-static material usage, preliminary user discharge and the wearing of anti-static clothing. If the IEC 60417-5134 ESD symbol is adjacent to a connetor, all the precautions of use must be taken before all handling.
Electrical fast Transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input output lines	± 2 kV for power supply lines ± 1 kV for input output lines	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical domestic, commercial or hospital environment. For a very exposed establishments or building with the lightning, a protection must be installed on mains power.
Voltage dips, short interruptions and voltage variations on power supply input lines **IEC 61000-4-11**	< 5 % Ut (> 95 % dip in Ut) for 0,5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles < 5 % Ut (> 95 % dip in Ut) for 5 s	< 5 % Ut (> 95 % dip in Ut) for 0,5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles < 5 % Ut (> 95 % dip in Ut) for 5 s	Mains power quality should be that of a typical domestic, commercial or hospital environment. For a short and long interruptions (< than battery autonomy) of power mains, the internal battery provide the continuity of service. For a very long (≥ than battery autonomy) interruptions of power mains, the **Base Intensive** must be powered from an external uninterruptible power supply (UPS).
Power frequency (50 / 60 Hz) magnetic field **IEC 61000-4-8**	400 A / m	400 A / m	If necessary, the power magnetic field should be measured in the intended installation location to assure that it is lower than compliance level. If the measured field in the location in which the **Base Intensive** is used exceeds the applicable magnetic field compliance level above, the Base Intensive should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or re-locating the **Base Intensive**, or install magnetic shielding.
Note: Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity TABLE 204

The **Base Intensive** is intended for use in the electromagnetic environment specified below. The user of **Base Intensive** should make sure it is used in such an environment.

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Conducted RF **IEC 61000-4-6**	3 Vrms 150 KHz to 80 MHz	10 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the **Base Intensive**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of transmitter.
Radiated RF **IEC 61000-4-3**	10 V / m 80 MHz to 2,5 GHz	10 V/m	Recommended separation distance: ■ D = 1,2 √ P , for a frequency of 150 KHz to 80 MHz ■ D = 1,2 √ P , for a frequency of 80 MHz to 800 MHz ■ D = 2,3 √ P , for a frequency of 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *D* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than compliance level. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to the fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Base Intensive** is used exceeds the applicable RF compliance level above, the **Base Intensive** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or re-locating the **Base Intensive**, or install magnetic shielding.

Recommended separation distances between portable and mobile RF communication equipment and the Base Intensive - TABLE 206

The **Base Intensive** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the **Base Intensive** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters)and the Base Intensive as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter in metres (m)		
	150 KHz to 80 MHz **d = 1,2 √ P**	**80 MHz to 800 MHz** **d = 1,2 √ P**	**800 MHz to 2,5 GHz** **d = 2,3 √ P**
0,01	**0,12**	**0,12**	**0,23**
0,1	**0,38**	**0,38**	**0,73**
1	**1,2**	**1,2**	**2,3**
10	**3,8**	**3,8**	**7,3**
100	**12**	**12**	**23**

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Maintenance recommendations

Cleaning and disinfecting

The Base Intensive is part of the patient's immediate environment. It is advisable to clean and disinfect the device's external surfaces on a daily basis in order to protect patient and staff.

■ Disconnect the base from its main supply before cleaning.

■ Do not place in an AUTOCLAVE nor IMMERSE the device. Do not let liquids enter the device's casing.

■ If the device is placed in a high contamination risk unit, it is advisable to leave it in the room during disinfecting, after having disinfected it with a moist cloth.

■ Use a cloth soaked in DETERGENT-DISINFECTANT previously diluted with water if required, to destroy micro-organisms. Avoid abrasive scrubbing which could scratch the casing. Do not rinse or wipe surfaces.

■ Do not use: TRICHLOROETHYLENE-DICHLOROETHYLENE - AMMONIA - AMMONIUM CHLORIDE - CHLORINE and AROMATIC HYDROCARBON - ETHYLENE DICHLORIDE-METHYLENE CHLORIDE - CETONE. These aggressive agents could damage the plastic parts and cause device malfunction.

■ Take care also with ALCOHOL BASED SPRAYS (20% - 40% alcohol). They lead to tarnishing of and small cracks in the plastic, and do not provide the necessary cleaning prior to disinfecting. Disinfecting SPRAYS may be used, in accordance with the manufacturer recommendation, from a distance of 30 cm of the device, avoid the accumulation of the product in liquid form.

Please contact the appropriate service, responsible for cleaning and disinfecting products, in your establishment for further details.

Environmental conditions

The device should be stored in a dry and cool place. In case of prolonged storage, the battery should be disconnected via the battery access flap situated underneath the device. This should be done by a qualified technician.

■ **Storage conditions and carrying**.

Temperature: 10°C + to 60°C.

Pressure:500 hPa to 1060 hPa.

Humidity: 10% to 90%, no condensation

■ **Use conditions**:

Temperature: 5°C to 40°C.

Pressure:700 hPa to 1060 hPa.

Humidity: 20% to 90%, no condensation.

Quality control

Upon the hospital request, a control check of the device is recommended every 12 months.

A regular control check (not included in the guarantee) consists of various inspection operations listed in the Technical manual. These control checks must be performed by an experienced technician and are not covered by any contract or agreement provided by Fresenius Vial.

Preventive maintenance

To ensure normal performance of the device, it is recommended that preventive maintenance is performed every 3 years. This includes battery replacement and it should be performed by a qualified technician.

The qualified technicians in your establishment or our After-Sales Service should be informed if the device is dropped or if any of malfunctions occurs. In this case, the device must not be used.

Caution: Failure to comply with these maintenance procedures can damage the device and lead to a functional failure. Internal inspection of the device requires the respect of particular procedures to void damages to the pump or user.

Servicing

For further information concerning the device servicing or use, please contact our After-Sales Service or our Customer service.

If a device is returned to our After-Sales Department, it is essential to clean and disinfect it, then, pack it very carefully, if possible in its original packaging, before sending it.

Fresenius Vial is not liable for loss or damage to the device during transport to our After-Sales Department.

⚠ At the end of the device life, return it to an organization competent in the treatment of the electrical and electronic equipment waste. Remove the battery from the device and return it to a competent recycling organization.

Function with the internal battery

The Base Intensive has an internal battery which automatically takes over when the mains supply is disconnected and ensures normal function with no loss of the programmed data.

Operation from the battery is visualized by the indicator (mains disconnection alarm).

Recharging the battery

To recharge battery, just connect the **Modules** to the **Base Intensive** and then to the mains power supply.

Recharging of the battery is visualised by the main indicator .

Recommendations

The battery should be replaced every three years or according your local servicing recommendations.

In order to preserve the pump's memory, it is recommended to recharge battery at least one time per month even if the pump has never been powered on.

Accessories

***Fresenius Vial* recommends the use of Orchestra® range accessories.**

Multifix 4 – Cat # 073804
Multifix 6 – Cat # 073809
Multifix 8 – Cat # 073805

This system simplifies transport and fastens safety of Orchestra® fitted with 4, 6 or 8 Modules. It can be installed on the Rolling Stand 180, on the Orchestra® Mobile Stand, on a pole or on two horizontal rails.

Warning: from the 4th Module onwards, Orchestra® must be equipped with the Multifix accessory to ensure rigidity.

(eg Multifix 4)

When the Base is used with one or several Modules, ***Fresenius Vial*** recommends the transport be done with the Multifix accessory by the handle.

During transportation of Orchestra® with Multifix accessory, only install maximum 6 Modules on the Base.

Mobile hooks for Multifix
(for Multifix cat # 073804/809/805**)**
Cat # 073800

RS 232 cord
Cat. # 073413 (9m/9f)
Cat. # 073414 (9m/25)

Otherwise, please use a lead whose length is 3 meters maximum.

Mainy Mod
Cat # 073807 (European plug)
Cat # 073810 (British plug)

External power source.

Orchestra® Mobile Stand

Whatever maybe the architecture of your department, Orchestra® Mobile Stand provides the choice of customized accessories.

❶ Orchestra® Rolling stand
Cat # 073076

❷ Fixing part handle for mobile hooks and mobile arm
Cat # 073079

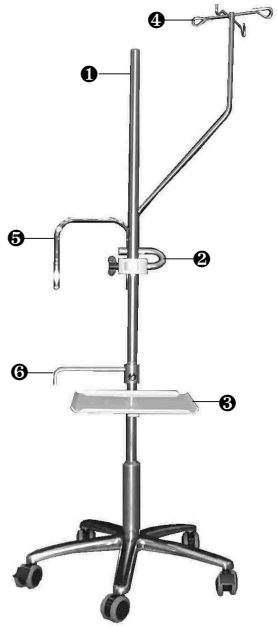
❸ Working table
Cat # 073077

❹ I.V pole 4 hooks
Cat # 073078 (*)

❺ Mobile arm support for IV pressure measurement
Cat # 073081 (*)

❻ Multichannel stop-cock support - Cat # 073080

(*) Accessories to be used with the Fixing part accessory cat # 073079.



Conditions of guarantee

Fresenius Vial guarantee that this product is free from defects in material and workmanship **during the period defined by the conditions of sale accepted**, except for the batteries and accessories.

To benefit from the materials and workmanship guarantee from our After-Sales Service or agent authorized by ***Fresenius Vial***, the following conditions must be respected:

- The device must have been used according to the instructions in this Operator's Guide.
- The device must not have been damaged when in storage, at the time of repair, or show signs of improper handling.
- The device must not have been altered or repaired by non-qualified personnel.
- The serial number (ID/N°) must not have been altered, changed, or erased.
- In case of non-respect of these conditions, ***Fresenius Vial*** will prepare an estimate for repair covering the parts and labor required.
- When return and repair of a device is necessary, please contact ***Fresenius Vial*** Customer or After-Sales Department.

Useful addresses

All requests for information or documentation (technical files, tubing sets catalogue or brochures) must be sent to:

CUSTOMER SERVICE - AFTER-SALES SERVICE:

Fresenius Vial
Le Grand Chemin
F-38590 BREZINS (France)

Tel: +33 (0)4 76 67 10 10
Fax: +33 (0)4 76 67 11 34
E-mail : customers.vial@fresenius-hemocare.com

Consult our Web site
www.fresenius-vial.fr

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Modifications may thus be made and will be included in later editions.

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